

November 22, 2004

Division of Dockets Management Food and Drug Administration, HHS 5630 Fishers Lane, Room 1061 Rockville, MD 20852

RE: Docket Nos. 1996P-0418, 1997P-0197, 1998P-0203 & 2000N-0504; Prevention of *Salmonella Enteritidis* in Shell Eggs During Production: Proposed Rule

Dear Sir or Madame:

On behalf of Farm Sanctuary and its 100,000 U.S. members, I wish to submit comments on the proposed rule to prevent *Salmonella enteritidis* (SE) in shell eggs, published in the *Federal Register* on September 22, 2004.

Farm Sanctuary supports the intent of the Food and Drug Administration (FDA) to establish regulations addressing the occurrence of Salmonella in shell eggs during production. SE continues to pose a significant threat to members of the American public who consume shell eggs. As observed in the *Federal Register* notice, SE illnesses in the U.S. have remained essentially steady for the past several years, despite a goal set in the year 2000 to reduce SE outbreaks and foodborne contamination by 50 percent by the year 2010. The incidence of SE remains much higher than in the 1970s, with an estimated 2.3 million SE-contaminated eggs consumed annually. The Centers for Disease Control and Prevention estimates that these contaminated eggs caused 118,000 illnesses in 2001.

Forced Molting Should Be Banned

In 1998 a SE risk assessment model for shell eggs and egg products, developed jointly by the FDA and the Food Safety and Inspection Service, predicted that using multiple interventions could achieve a more substantial reduction in SE illnesses than using any one intervention alone. While the FDA is now proposing a number of prevention measures to address SE contamination, it is not including a ban on induced or forced molting, a practice that has been demonstrated to be associated with SE infection and transmission among laying hens.

For the purpose of these comments, forced molting refers to the process of artificially inducing a molt in laying hens by limiting or withdrawing feed, water, and/or light. Forced molting programs typically deprive hens of feed for 14 days or more and cause body weight losses of 25 to 35% (1). According to the 1999 Layers Study, conducted by the National Animal Health Monitoring System and cited in the FR notice, 83 percent of

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U.S. egg-laying farms use forced molting. However, the practice is much more common among large operations, with 85 percent of facilities with 50,000 or more layers molting their birds, and only 28 percent of farms with fewer than 20,000 layers molting their flocks. Currently, there are 65 U.S. egg producing companies with more than 1 million layers (2). In order to maximize profits, this relatively small number of very large egg producers has managed to keep forced molting of hens legal, despite serious concerns over the animal welfare and public health impacts.

In arguing that forced molting should be prohibited, animal protection advocates cite cruelty to laying hens and the association between the practice and SE infection and transmission. We believe both of these rationale are valid.

Forced Molting Causes Animal Stress

The FDA's response to the argument of animal cruelty is that this issue is outside the scope of the proposed rule. We disagree. Other countries routinely consider animal welfare impacts in setting policy and regulations related to food safety. Various forms of animal neglect, abuse, and cruelty are prohibited under all 50-state animal cruelty statutes and under the federal Animal Welfare and Humane Methods of Slaughter Acts. Moreover, it is known that stress causes both human and non-human animals to be more susceptible to disease, a fact that is directly relevant to the goal of preventing SE contamination of shell eggs.

Dr. Ian Duncan, Professor of Poultry Ethology at the University of Guelph, Canada, and author of more than 150 papers on poultry welfare, describes withholding feed from hens as "starvation" and observes that force molting causes hens to suffer enormously (3). He notes that hunger is an extremely powerful motivation in chickens and, as a result, food deprivation for forced molting results in severe physiological stress to hens. Evidence of this stress has been demonstrated in a number of research studies, including the following:

- Meat chickens on restricted feed are chronically hungry (4), show behaviors indicative of boredom and frustration (5), and are more aggressive (6).
- In one study, hens deprived of food for 3 days increased cage-pecking activities by a factor of 3 and feather pecking by a factor of 8 (7).
- In another study hens deprived of feed for 21 days at first showed increased aggression and non-nutritive pecking and later showed inactivity, suggesting debilitation (8).
- Feed withdrawal or reduction in chickens causes increased concentrations of plasma corticosterone, an indicator of stress (9).
- Heterophil to lymphocyte ratios, considered the most reliable physiological index of stress in birds, also increase as a result of feed restriction (10).
- 48 hours of feed deprivation in chickens results in increased susceptibility to S. aureus (11).

In addition, mortality – an indicator of both animal health and animal welfare – has been shown to increase dramatically during forced molting. Dr. Donald Bell, of the University of California-Riverside, summarized molting results from 353 U.S. layer flocks during 1997-1998 and observed that mortality doubled during the first week of a molt and doubled again during the second week (12).

Forced Molting is Associated with SE Infection and Transmission

The FR notice acknowledges that SE experts now believe that the predominant route by which eggs become contaminated is through the ovaries and oviducts of egg-laying hens, allowing contamination of the interior of the egg while still inside the hen. The research cited above offers support for the argument that forced molting is stressful to laying hens, impairs their immune system and, thereby, encourages SE infection. Several studies have demonstrated an association between the practice of forced molting and SE infection in laying hens, including the following:

- Significantly more SE is shed in forced molted than non-molted hens (13-16), and significantly more fasted birds than non-fasted birds become positive for SE after contact exposure (13, 17).
- Horizontal transmission of SE to previously uninfected but contact-exposed hens in adjacent cages is higher among molted than non-molted birds (16, 17).
- Post infection, the numbers of SE recovered from alimentary, liver, spleen (18, 19) and ovary (19) samples is significantly higher in molted than non-molted birds. Molted hens exhibit more intestinal inflammation (20).
- Studies conducted for the Salmonella enteritidis Pilot Project on commercial flocks in Pennsylvania showed an increase in the incidence of eggs contaminated with SE from 0.02 percent in the 5 weeks before the molt to 0.144 percent in the 5 weeks following the molt (20).

The FR notice also acknowledges that some research findings, specifically those obtained for the Salmonella Enteritidis Pilot Project, suggest a link between molting and production of SE-contaminated eggs. However, the agency expresses several concerns about the conclusiveness of the data related to the methodology employed in the various studies and the application of laboratory findings to field situations. A number of studies related to forced molting and SE have been conducted by the Agricultural Research Service of the U.S. Department of Agriculture over the past 10-15 years. Without exception, they documented a connection between forced molting and SE in laying hens. The notice does not explain why the USDA would repeatedly conduct studies with limited application or why the FDA did not convey these concerns regarding research methodology during this extended period of time.

Laboratory evidence has shown that forced molting results in increased SE infection among hens, and that hens with SE infections are capable of producing contaminated eggs. In addition, field data suggests a direct link between force molting and SE contamination of eggs. Therefore, we believe there is adequate scientific justification for prohibiting the practice.

Support for a Ban on Forced Molting

Many animal production and veterinary professionals now agree with animal protection advocates that feed deprivation for forced molting causes animal suffering and stress and should be ended. The United Kingdom has enacted a prohibition on the withdrawal of food, water, and lighting for forced molting. McDonald's and Wendy's corporations have established policies against the use of forced molting by their egg suppliers in the U.S. and internationally. In addition, the Certified Humane and Free Farmed food certifications programs disallow the practice. In 2002, the joint animal welfare program of the Food Marketing Institute and the National Council of Chain Restaurants requested that the U.S. egg industry develop a specific phase-out program for feed-withdrawal molting, and, consequently, in 2003 the scientific advisory committee of the United Egg Producers approved a non-feed withdrawal molt program. Finally, at its 2004 convention the American Veterinary Medical Association approved a resolution in opposition to the withholding of water or food from laying hens for forced molting, noting, "The welfare of birds should be a major consideration in this and any management practice."

A direct connection exists between the welfare of farmed animals and their health. Research has demonstrated that 1) forced molting by feed restriction causes stress to animals, 2) hens undergoing forced molting have an increased incidence of SE infection, and 3) infected hens can transmit SE to their eggs. The FDA should acknowledge the role of forced molting in SE contamination of shell eggs and prohibit the practice.

Thank you for providing Farm Sanctuary the opportunity to comment on an issue of great interest to our members.

Sincerely,

Gene Bauston, President

Farm Sanctuary, Inc.

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